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EXAMINER

BALL, JOHN C

ART UNIT

PAPER NUMBER

1759

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,939	Applicant(s) VIGH ET AL.	
	Examiner J. CHRISTOPHER BALL	Art Unit 1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This Office Action is based on the Amendment filed with the Office on October 26, 2010, regarding the VIGH et al. application.
2. Claims 1-58 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 14-16, 18, 25, 26, and 50-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of the claims have been amended to recite an ion conduit, however the instant disclosure as filed makes no mention of an ion conduit, nor could the Examiner identify an element that would constitute an ion conduit. For

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examination purposes with respect to the prior art, an ion conduit will be considered to be an element that allows flow of ions.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Both claims essentially attempt to claim a device based on what is "shown and described" by Figures of the original disclosure. This is not an adequate claim to define the metes and bounds the device, and therefore the claims are indefinite.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 1-4, 6-14, 16-19, 21-25, 27-51, 54, 55, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAMMONS et al. (US 5,662,813) in view of TARNOPOLSKY (US 5,032,247), as evidenced by the webpage entitled "Crystal Quartz (SiO₂) and Fused Silica" (http://www.mt-berlin.com/frames_cryst/descriptions/quartz%20.htm), printed March 21, 2005, herein after "WEBPAGE"), all submitted to the Office on an Information Disclosure Statement.

Regarding claims 1, 16, 50, and 51, SAMMONS discloses an electrophoresis apparatus, comprising: an anode and cathode disposed in respective compartments (61 and 64, Figure 5) with ports for addition or removal of a solution (11 and 13, Figure 2), the compartments inherently having a width dimension, substantially orthogonal to the direction of the electric field, a depth dimension, substantially orthogonal to the direction of the electric field and substantially orthogonal to the width, and a length dimension, substantially

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parallel to the electric field and substantially orthogonal to both the width and depth;

the anode and cathode compartments were filed with buffer (Col. 6, lines 59-64); which the is part of the sample, as nucleated fetal red blood cells are suspended in buffer (Col. 8, lines 28-35);

ion-permeable barriers that prevent convective mixing (17, Figure 4) disposed between the compartments, the ion-permeable barriers constitute ion conduits in that they permit ion flow;

separate compartments disposed between the anode and cathode compartments (Figure 5);

and with a portion of each compartment (cooling lines 14, Figures 3-4) made from a heat-conductive material, optionally ceramic (Col. 5, lines 49-55). SAMMONS additionally teaches an aspect ratio of 1/250 (Col. 4, lines 30-34).

SAMMONS does not explicitly recite that the material composing the compartments has a given value for either thermal conductivity or specific heat.

However, TARNOPOLSKY discloses a membrane separation apparatus, wherein is taught a coolant is flowed through hollow silica fibers in the chambers (Abstract). It is shown by the WEBPAGE that the thermal conductivity of fused silica is 1.46 W/m·K and the specific heat of fused silica is 670-740 J/K·kg.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus as taught by SAMMONS by utilizing the silica, as taught by TARNOPOLSKY, as the cooling line comprising a

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part of the compartments because the silica would more efficiently conduct heat than plastic materials, resulting in more effective cooling that suggested by SAMMONS in utilization of ceramics for this purpose. (SAMMONS, Col. 5, lines 49-55).

Regarding claims 2-4 and 17-19, SAMMONS teaches polymeric sealing material between the compartments (Col. 4, lines 34-43).

Regarding claims 6-8 and 21-23, SAMMONS teaches housing comprising ceramic materials (Figure 2-4, 12, and 14; Col. 5, lines 49-55).

Regarding claims 9 and 24, SAMMONS teaches an electrically insulating material as part of the anode and cathode compartments as a generic ceramic, while TARNOPOLSKY discloses a membrane separation apparatus, wherein is taught a coolant is flowed through hollow silica fibers in the chambers (Abstract).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus as taught by SAMMONS by utilizing the silica, as taught by TARNOPOLSKY, as the cooling line comprising a part of the compartments because the silica would more efficiently conduct heat than plastic materials, resulting in more effective cooling that suggested by SAMMONS in utilization of ceramics for this purpose. (SAMMONS, Col. 5, lines 49-55).

Regarding claims 10-13, 32-35, and 38-41, SAMMONS teaches chambers with an aspect ratio of 1/250 (Col. 4, lines 30-34).

Regarding claims 14, 25, and 54, SAMMONS teaches woven polymer membranes, which would be essentially free from weakly acidic or basic functional groups, anionic functional groups, and cationic functional groups (Col. 4, lines 44-48).

Regarding claim 27-30, SAMMONS teaches a first dimension being as low as 2 mm (Col. 4, lines 30-34). It has been held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984)).

Regarding claims 31, 48, and 49, SAMMONS teaches at least first and second separation compartment (Figure 5). It has been held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative

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dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984)).

Regarding claims 36 and 37, SAMMONS teaches the third dimension of the at least one separation compartment is less than 1/2 or 1/3 of the distance between the anode and cathode (Col. 4, lines 30-34).

Regarding claims 42-47, SAMMONS teaches an apparatus with twelve separation compartments (Figure 5). It has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced (*In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

Regarding claim 55, SAMMON, as modified by TARNOPOLSKY, teaches the apparatus of claim 1. SAMMON also discloses a method for altering a composition of a sample by electrophoresis, the method comprising:

selecting an ion-permeable barrier for use between the anode and cathode compartments (17, Figure 4; Col. 4, lines 44-52);

providing electrolytes to the anode and cathode compartments (Col. 3, lines 51-52);

providing the sample to at least one of the compartments (58 to 72 to 73, Figure 5);

creating an electrophoretic direct current between the anode and cathode by applying an electrical potential between the anode and cathode (Col. 3, lines 47-50); and

causing a transfer of at least one part of at least one component of the sample across the ion-permeable barrier (Col. 8, lines 12-19), which is an ion conduit.

Regarding claim 56, SAMMON, as modified by TARNOPOLSKY, teaches the apparatus of claim 16. SAMMON also discloses a method for altering a composition of a sample by electrophoresis, the method comprising:

selecting an ion-permeable barrier for use between the anode and cathode compartments (17, Figure 4; Col. 4, lines 44-52);

providing at least one electrolyte to any of the compartments free of the sample (90, Figure 5);

providing the sample to at least one of the compartments (58 to 72 to 73, Figure 5);

creating an electrophoretic direct current between the anode and cathode by applying an electrical potential between the anode and cathode (Col. 3, lines 47-50); and

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causing a transfer of at least one part of at least one component of the sample across the ion-permeable barrier (Col. 8, lines 12-19), which is an ion conduit.

10. Claims 5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAMMONS et al. (US 5,662,813) in view of TARNOPOLSKY (US 5,032,247), as evidenced by the webpage entitled "Crystal Quartz (SiO₂) and Fused Silica" (http://www.mt-berlin.com/frames_cryst/descriptions/quartz%20.htm, printed March 21, 2005, herein after "WEBPAGE") as applied to claims 1-4, 6-14, 16-19, 21-25, 27-51, 54, 55, and 56 above, and further in view of CHLANDA et al. (US 5,126,026), submitted to the Office on an Information Disclosure Statement.

Regarding claim 5 and 20, SAMMONS, as modified by TARNOPOLSKY, teaches the limitations of claim 1-4 and 16, 17, and 19, as outlined above.

SAMMONS also teaches utilizing silicone rubber for sealing, but does suggest use of other suitable materials (Col. 4, lines 35-43).

SAMMONS and TARNOPOLSKY do not explicitly teach use of a material selected from the group consisting of polyethylene, polypropylene, polyisobutylene, polyalkylenes, polyfluorocarbons, poly(dimethylsiloxane), poly(diallcylsiloxane), poly(alkylarylsiloxane), poly(diarylsiloxane), poly(ether ether ketones) or a combination thereof.

However, CHLANDA discloses guard membranes for using in electrodialysis cell, wherein is taught polyethylene gaskets for sealing chambers (Col. 13, lines 34-37 and 47-51).

At the time of the present invention, the substitution of one known material, the polyethylene as taught by CHLANDA, for another, the silicone rubber as taught by SAMMONS, would have yield predictable result to one of ordinary skill in the art (*KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007)).

11. Claims 15, 26, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAMMONS et al. (US 5,662,813) in view of TARNOPOLSKY (US 5,032,247), as evidenced by the webpage entitled "Crystal Quartz (SiO₂) and Fused Silica" (http://www.mt-berlin.com/frames_cryst/descriptions/quartz%20.htm, printed March 21, 2005, herein after "WEBPAGE") as applied to claims 1-4, 6-14, 16-19, 21-25, 27-51, 54, 55, and 56 above, and further in view of EGEN et al. (US 5,173,164), submitted to the Office on an Information Disclosure Statement.

Regarding claim 15, 26, 52, and 53, SAMMONS, as modified by TARNOPOLSKY, teaches the limitations of claims 1, 16, and 51, as outlined above.

SAMMONS and TARNOPOLSKY do not explicitly teach the barriers are isoelectric barriers.

However, EGEN discloses a multi-modal electrical separator, wherein is taught membranes which could fairly be considered isoelectric barriers, given the specific buffer system specified (Col. 8, lines 33-49).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the barriers as taught by SAMMONS with the barriers as taught by EGEN because SAMMONS explicitly suggest suitable usage of the disclosed system and method of EGEN by incorporating by reference the disclosure of EGEN (SAMMONS, Col. 2, lines 2-6).

Response to Arguments

12. Applicant's arguments filed October 26, 2010, have been fully considered but they are not persuasive. First, Applicant argues the amendment to claims 57 and 58 have rendered moot the rejections under 35 USC 112, second paragraph. However, since these claims attempt to claim devices only in reference to Figures, they are indefinite.

Next, Applicant argue that, as amended, the independent claims are patentable over the prior art for the following reasons: a) that SAMMONS fails to teach an anode or cathode compartment that is configured to hold at least a portion of a sample, b) that the anode and cathode compartments of SAMMONS

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are closed off and therefore do include a first, second, or third compartment orthogonal to the electric field, and c) SAMMONS does not teach the claimed ion conduits. However, the anode and cathode compartment of SAMMONS are configured to hold buffer, which is combined with the analyte of interest, nucleated fetal red blood cells, constitute the sample. Additionally, SAMMONS teaches compartments between the anode and cathode, and that the claims do not recited the anode and cathode compartments include a first, second, and third compartments. Finally, SAMMONS teaches an ion permeable barrier, which functions as an ion conduit.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 9 am to 5 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571) 272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCB
01/01/2011

/Ula C Ruddock/
Supervisory Patent Examiner, Art Unit 1795